

Appl. No. 10/630,330

Preliminary Amdt dated: February 9, 2005

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

Claim 1. (original) A method for determining an elasticity coefficient of a target, comprising the steps of:  
determining simultaneously two or more critical-angle reflections of an ultrasound wave from the target using an ultrasound transducer comprising a transmitter and two or more receivers; and calculating the elasticity coefficients of the target.

Claim 2. (original) The method of claim 1, wherein the target comprises bone.

Claim 3. (original) The method of claim 1, wherein the target comprises human bone.

Claim 4. (original) The method of claim 1, wherein the target comprises a human bone from a human being suffering from or suspected of having osteoporosis.

Claim 5. (original) The method of claim 1, wherein the target comprises bone from a human being suffering from or suspected of having osteoporosis under treatment with bisphosphonate.

Claim 6. (original) The method of claim 1, wherein the detection step is non-invasive.

Claim 7. (original) The method of claim 1, wherein one or more elasticity coefficients are determined from the square of ultrasound velocity as determined from the identified critical angle.

Claim 8. (original) The method of claim 1, further comprising the steps of:  
determining a maximum elasticity coefficient and a minimum elasticity coefficient to estimate a degree of target anisotropy; and

using the critical-angle reflection values detected at multiple rotational orientations from the ultrasound transducer fixed at a position normal to a bone surface.

Claim 9. (original) The method of claim 2, further comprising the step of determining a maximum elasticity coefficient and a minimum elasticity coefficient to estimate a degree of bone anisotropy.

Claim 10. (original) The method of claim 1, further comprising the step of automating the determination of the normal of the transducer to the target.

Claim 11. (original) The method of claim 1, wherein the step of detecting simultaneously is further defined as comprising the simultaneous reception from 2, 4, 8, 16, 24, 36, 48, 64 or 128 receivers.

Claim 12. (original) The method of claim 1, further comprising the step of storing the critical-angle values detected in the reflection of an ultrasound wave at two or more receivers that are concentric with a transmitter.

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Claim 13. (original) The method of claim 1, wherein comprising the steps of:  
storing the detected critical-angle reflections of ultrasound waves at different points in time; and  
comparing the measurements to track changes in the coefficient of elasticity of the target.

Claim 14. (original) The method of claim 1, wherein the step of detecting at two or more angles uses a transducer head comprising at least one transmitter and two or more receivers that detect simultaneously the reflected ultrasound energy from the target, wherein the transmitter and the two or more transducers have a common focal point.

Claim 15. (original) The method of claim 1, wherein the transmitter is concave.

Claim 16. (original) The method of claim 1, wherein the two or more receivers form part of a concave array in at least two dimensions.

Claim 17. (original) The method of claim 1, wherein the transmitter and the two or more receivers are concave and concentric.

Claim 18. (original) The method of claim 1, wherein the transmitter is concave and the two or more receivers are concave and the transmitter and the two or more receivers are concentric about a common focal point.

Claim 19. (original) The method of claim 1, wherein the receivers are further defined as a receiving array and the array comprises 48 independent receiving transducers that are concentric and concave and share a focal point with the transmitter.

Claim 20. (original) The method of claim 4, wherein the human has bone disease, a bone-losing condition other than osteoporosis, or a condition suspected of causing inferior bone strength.

Claim 21. (original) The method of claim 5, wherein the treatment of osteoporosis comprises drugs other than bisphosphonate, e.g., an estrogen, an estrogen analog, a parathyroid hormone peptide, a fluoride, a vitamin D, and a calcitonin.

Claim 22. (original) The method of claim 5, wherein the treatment is suspected of causing bone loss.

Claim 23. (original) The method of claim 5, wherein the treatment is suspected of causing bone loss caused by a steroid or anticonvulsant.

Claim 24. (original) The method of claim 5, wherein the step of detecting simultaneously two or more critical-angle reflections of an ultrasound wave from the target is taken prior to initiation of bisphosphonate treatment, in order to identify patients with inferior bone quality in whom bisphosphonate should be used with caution.

Claim 25. (original) A method for determining the effect on a coefficient of elasticity of bone from a patient undergoing treatment for osteoporosis, comprising the steps of:

detecting simultaneously at two or more angles the critical-angle reflections of ultrasound waves directed at a bone using an ultrasound transducer with one or more transmitters and two or more receivers; and

calculating the anisotropy of the bone from the ratio of a maximum elasticity coefficient and a minimum elasticity coefficient, wherein elasticity coefficients are derived as the square of the

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velocities of an ultrasound waves as determined from the critical angle.

Claim 26. (original) The method of claim 25, wherein comprising the steps of:

storing a first detected critical-angle reflection of ultrasound waves at two or more receivers prior to, or concurrent with, treatment with a bisphosphonate or derivative thereof;

storing a second detected critical-angle reflection of ultrasound waves at two or more receivers after a period of time; and

comparing the first and second measurements to track changes in the elasticity coefficient of the bone during treatment with the bisphosphonate or derivative thereof.

Claim 27. (original) The method of claim 25, wherein the step of detecting simultaneously at two or more angles the critical-angle reflection of ultrasound waves directed at a bone using an ultrasound transducer further comprises measuring a maximum and a minimum elasticity of a cortical and a trabecular region of the bone; and

estimating the anisotropy of the bone in vivo.

Claim 28. (original) The method of claim 27, wherein determining the elasticity of cortical bone, trabecular bone, and anisotropy of a patient's bone is non-invasive.

Claim 29. (original) The method of claim 28, wherein the measurement of elasticity is at a heel.

Claim 30. (original) The method of claim 28, wherein the step of calculating the anisotropy of the bone further comprises determining the maximum and the minimum elasticity coefficient of a cortical and a trabecular bone region, wherein the measurements correspond to an axis of a weight-bearing and a non-weight-bearing bone, respectively.

Claim 31. (original) The method of claim 25, wherein the patient has bone disease, a bone-losing condition other than osteoporosis, or a condition suspected of causing inferior bone strength.

Claim 32. (original) The method of claim 26, wherein the treatment of osteoporosis comprises an estrogen, an estrogen analog, a parathyroid hormone peptide, a fluoride, a vitamin D, and a calcitonin.

Claim 33. (original) The method of claim 26, wherein the treatment is suspected of causing bone loss caused by steroid or anticonvulsant.

Claim 34. (original) The method of claim 26, wherein the step of detecting simultaneously two or more critical-angle reflections of an ultrasound wave from the target is prior to initiation of bisphosphonate treatment, in order to identify patients with inferior bone quality in whom bisphosphonate should be used with caution.

Claim 35. (canceled)

Claim 36. (original) A transducer comprising:

at least one ultrasound transmitter; and

two or more receivers separated by an angle that form a receiver array and is concentric and shares a focal point with the transmitter and, wherein the receiver array detects simultaneously the reflected ultrasound energy from a target. (original)

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Claim 37. (original) The transducer of claim 36, wherein the transmitter is concave in at least two dimensions.

Claim 38. (original) The transducer of claim 36, wherein the two or more receivers that form part of a concave array in at least two dimensions.

Claim 39. (original) The transducer of claim 36, wherein the transmitter and the two or more receivers are concave and concentric.

Claim 40. (original) The transducer of claim 36, wherein the transmitter is concave and the two or more receivers are concave and the transmitter and the two or more receivers are concentric about a common focal point.

Claim 41. (original) The transducer of claim 36, wherein the receivers are further defined as a receiving array and the array comprises 2, 4, 8, 16, 24, 36, 48, 64 or 128 independent receivers.

Claim 42. (original) The transducer of claim 36, wherein the array system is comprised of a single transmitter and a 48-element receiver array located in a housing, wherein the receiver array measures simultaneous the velocity of an ultrasound wave across 120 degrees from a point of examination that is at or about the focal point of the transmitter.

Claim 43. (original) The transducer of claim 36, further comprising a housing for the transmitter and the at least two receivers, the housing having at least one opening at or about the focal point of the transmitter and receivers.

Claim 44. (original) The transducer of claim 36, further comprising:

a housing for the transmitter and the at least two receivers, the housing having at least one opening;

a latex membrane at or about the opening of the housing; and

an ultrasound conductive material within the housing.

Claim 45. (original) The transducer of claim 44, wherein the ultrasound conductive material comprises water.

Claim 46. (original) The transducer of claim 36, further comprising a computer-controlled positioning arm connected to the transducer, wherein movement of the transducer permits accurate positioning of device on a point of examination.

Claim 47. (original) The transducer of claim 44, further comprising a pressure detector in communication with the ultrasound conductive material, which detects the increase in pressure within the housing that may break the latex membrane.

Claim 48. (original) The transducer of claim 36, further comprising at least one computer connected to transmitter and receivers of the transducer, the computer comprising at least one code segment that gathers one or more reflected spectra from each receiver at each angle, and calculates from the spectra the critical angles for a cortical and a trabecular bone.

Claim 49. (original) The transducer of claim 48, wherein the computer further comprises at least one code segment that determines critical-angle velocities, and fits them to a linear-quadratic equation for the determination of at least two principal coefficients of elasticity.

Claim 50. (original) A transducer comprising:

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at least one ultrasound transmitter; and

a receiver array that is concentric and shares a focal point with the transmitter, wherein the receiver array detects simultaneously the reflected ultrasound energy from a target at multiple angles.

Claim 51. (original) The transducer of claim 50, wherein the transmitter is concave in at least two dimensions.

Claim 52. (original) The transducer of claim 50, wherein the receiver array comprises a concave array in at least two dimensions.

Claim 53. (original) The transducer of claim 50, wherein the receiver array comprises 2, 4, 6, 12, 24, 36 or 48 independent receiving transducers.

Claim 54. (original) The transducer of claim 53, wherein the transducer comprises a single transmitter and the receiver array, wherein the receiver array measures simultaneously the velocity of an ultrasound wave across 120 degrees from a point of examination that is at or about the focal point of the transmitter.

Claim 55. (original) The transducer of claim 50, further comprising a housing for the transmitter and the receiver array, the housing having at least one opening at, about or adjacent to, the focal point of the transmitter and receiver array.

Claim 56. (original) The transducer of claim 50, further comprising:

a housing for the transmitter and the at least two receivers, the housing having at least one opening;

a latex membrane at or about the opening of the housing; and

an ultrasound conductive material within the housing.

Claim 57. (original) The transducer of claim 56, wherein the ultrasound conductive material comprises water.

Claim 58. (original) The transducer of claim 50, further comprising a computer-controlled positioning arm connected to the transducer, wherein movement of the transducer permits accurate positioning of device on a point of examination.

Claim 59. (original) The transducer of claim 50, further comprising a pressure detector positioned to contact the ultrasound conductive material detects when excessive pressure is applied to the latex membrane enclosing ultrasound conductive material within the housing.

Claim 60. (original) The transducer of claim 50, further comprising at least one computer connected to the transmitter and the receiver array.

Claim 61. (original) The transducer of claim 60, wherein the computer comprises at least one code segment that gathers one or more reflected spectra from the receiver array and calculates from the spectra one or more critical angles for a cortical and a trabecular bone.

Claim 62. (original) The transducer of claim 60, wherein the computer comprises at least one code segment that determines critical angle velocities, and fits the critical angle velocity to a linear-quadratic equation for the determination of at least two principal coefficients of elasticity.

Claim 63. (original) A system for measuring bone anisotropy comprising:

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a computer-controlled ultrasound critical-angle reflectometry transducer that detects ultrasound velocities at multiple angles simultaneously and automatically;

an articulated arm that permits motion in three-dimensions that supports the ultrasound transducer; and

a computer connected to and capable of receiving a signal from the ultrasound transducer to calculate critical-angle reflectometry data from the ultrasound transducer.

Claim 64. (original) The system of claim 63, wherein the computer is connected one or more controllers of the articulated arm that direct the position of the transducer in three dimensions.

Claim 65. (original) The system of claim 63, wherein the transducer measures elasticity coefficients of bone from a patient suffering from or suspected of having osteoporosis.

Claim 66. (original) The system of claim 63, wherein the transducer measures the elasticity coefficients of bone from a patient suffering from or suspected of having osteoporosis who was treated with bisphosphonate.

Claim 67. (original) The system of claim 63, wherein the computer determines an elasticity coefficient by comparing the square of the velocity of an ultrasound wave with the intrinsic orientation of bone at a fixed position using values detected at multiple orientations using the ultrasound transducer.

Claim 68. (original) The system of claim 63, wherein the computer calculates a maximum elasticity coefficient and a minimum elasticity coefficient to estimate a degree of target anisotropy.

Claim 69. (original) The system of claim 63, wherein the computer automates the determination of the normal of the transducer to the target.

Claim 70. (original) The system of claim 63, wherein computer receives simultaneously receiver data from 2, 4, 8, 16, 24, 36, 48, 64 or 128 different receivers.

Claim 71. (original) The system of claim 63, wherein the computer stores a detected critical-angle reflection value of an ultrasound wave at two or more receivers that are concentric with a transmitter.

Claim 72. (original) The system of claim 63, wherein the computer stores a value for critical-angle reflection of ultrasound waves at different points in time.

Claim 73. (original) The system of claim 63, wherein the computer stores a value for critical-angle reflection of ultrasound waves at different points in time to determine a coefficient of elasticity and tracks changes in the coefficient of elasticity of a target.

Claim 74. (original) The system of claim 63, wherein the number of receivers is an odd number greater than 1.

Claim 75. (original) The system of claim 63, wherein the computer determines the effect on an elasticity coefficient of a bone from a patient undergoing therapy for osteoporosis.

Claim 76. (original) The system of claim 63, wherein the computer determines the effect on an elasticity coefficient of bone from a patient undergoing therapy for osteoporosis by storing a first and a second value for the elasticity coefficient of a patient at a first and a second point in time, and calculates a bone anisotropy value from the ratio of a maximum elasticity coefficient and a

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minimum elasticity coefficient and tracks bone anisotropy over time.

Claim 77. (original) The system of claim 63, wherein the computer determines the effect on a coefficient of elasticity of bone from a patient undergoing bisphosphonate therapy for osteoporosis by storing a first and a second value for an elasticity coefficient of a patient at a first and a second point in time, and calculates a bone anisotropy value from the ratio of a maximum elasticity coefficient and minimum elasticity coefficient and tracks anisotropy over time in order to derive the effect of bisphosphonate treatment on bone quality.

Claim 78. (original) The system of claim 63, wherein the transducer is used to detect the ultrasound critical-angle reflectometry measurement at a heel.

Claim 79. (original) The system of claim 63, wherein the computer calculates the anisotropy of the bone further by determining a maximum elasticity coefficient and a minimum elasticity coefficient of a cortical and a trabecular bone region, wherein the measurements correspond to an axis of a weight-bearing and a non-weight-bearing bone, respectively.

Claim 80. (original) The system of claim 65, wherein the human has bone disease, a bone-losing condition other than osteoporosis, or a condition suspected of causing inferior bone strength.

Claim 81. (original) The system of claim 66, wherein the treatment of osteoporosis comprises an estrogen, an estrogen analog, a parathyroid hormone peptide, a fluoride, a vitamin D, and a calcitonin.

Claim 82. (original) The system of claim 66, wherein the treatment is suspected of causing bone loss.

Claim 83. (original) The system of claim 66, wherein the treatment is suspected of causing bone loss caused by a steroid or an anticonvulsant.

Claim 84. (original) The system of claim 66, wherein the critical-angle reflectometry measurements are made prior to initiation of bisphosphonate treatment, in order to identify patients with inferior bone quality in whom bisphosphonate should be used with caution.

Claim 85. (original) A method for simultaneously measuring maximum and minimum elasticity coefficients and anisotropy of bone non-invasively in vivo in accordance with the method of claim 1.

Claim 86. (original) A method for taking simultaneous measurements of maximum and minimum elasticity coefficients and anisotropy of cortical and trabecular bone non-invasively in vivo in accordance with the method of claim 25.

Claim 87. (original) A method for taking simultaneous measurements of maximum and minimum elasticity coefficients and anisotropy of cortical and trabecular bone non-invasively in vivo using the transducer of claim 36.

Claim 88. (original) A method for taking simultaneous measurements of maximum and minimum elasticity coefficients and anisotropy of cortical and trabecular bone non-invasively in vivo using the transducer of claim 50.

Claim 89. (original) A method for taking simultaneous measurements of maximum and minimum elasticity coefficients and anisotropy of cortical and trabecular bone non-invasively in vivo using the system of claim 66.